



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David R. MILLER et al.	Confirmation No.: 4583
Application No. 10/695,441	Art Unit: 3736
Filed: October 29, 2003	Examiner: Robert Nasser
For: BLADDER-BASED CUFF FOR MEASURING PHYSIOLOGICAL PARAMETERS AND METHOD OF MEASURING PHYSIOLOGICAL PARAMETERS USING SAME	Atty Docket: P67936US0

DECLARATION UNDER 37 C.F.R. § 1.132 OF DAVID BELL

Mail Stop AMENDMENT
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, DAVID A. BELL, declare that:

1. I am the David A. Bell who provided the Declaration Under 37 C.F.R. § 1.132 submitted with the response to the Office Action dated December 12, 2005 issued in connection with this application.
2. I have read and understand the Office Action dated May 25, 2006 issued in connection with this application, and U.S. Patent No. 6,801,798 to Geddes et al. ("the Geddes patent" or "Geddes") and U.S. Patent No. 5,807,266 to Itonaga ("the Itonaga patent" or "Itonaga") cited in the Office Action.
3. The Geddes patent describes an inflatable pressure cuff for measurement of systolic, mean, and diastolic pressure; oxygen saturation; pulse; and respiratory rate. At column 2,

line2 and column 3, line 51, Geddes describes the inflatable cuff 46 as being "optically transparent."

4. The Office Action recognizes that Geddes does not describe tinting of the bladder. The Itonaga et al. patent was cited as rectifying this deficiency through its asserted teaching of a black bladder for minimizing interference and light piping.
5. Geddes states at column 3, lines 32-39:

In order to facilitate use of the cuff on a bone-containing body member, i.e., to avoid bone shadow, two light sources 40 and 42 are circumferentially spaced on one housing section in opposition to a photodetector 44 mounted on the other housing section. This configuration increases the transmission of light through the tissue bed around the bone 45 in the member in which blood pressure is measured noninvasively.

Geddes further states at column 3, lines 58-60, that the inflatable cuff 46 is "made of material that is transparent to the wavelengths of light emitted by the LEDs." In other words, Geddes's cuff 46 is substantially completely transparent.

6. The Itonaga patent states at column 6, lines 40-46:

Another way to implement the windows would be to make outer cuff 2A black and reinforce its surface. Then outer cuff 2A would have low infrared transparency, and slits 20 could be provided in the portions of the cuff facing pulse sensors 10. This would make it difficult for stray light to strike the photodetectors in pulse sensors 10 and so would enhance their pulse detection function.

7. To a person of ordinary skill in the art, making the cuff black implies that it opaque; although as it is not physically possible to make an object perfectly opaque, it will have some nominal transparency. In my opinion, it is to this nominal transparency that Itonaga refers in stating that the cuff, if black, "would have low infrared transparency." In other words, Itonaga's outer cuff 2A is substantially completely opaque.

8. Although it would be possible to make Geddes's cuff 46 black as taught by Itonaga, this change would Geddes's device inoperative for its intended purpose, as an opaque cuff 46 would substantially impede the transmission of light through the tissue bed around the bone 45 in the member in which blood pressure is measured. It is therefore my opinion that one of ordinary skill in the art would not be motivated to make Geddes's cuff 46 black as taught by Itonaga.
9. Further, Geddes's cuff 46 and Itonaga's outer cuff 2A teach an "all or nothing" approach to transparency and opacity, with Geddes's cuff 46 being substantially completely transparent and Itonaga's outer cuff 2A being substantially completely opaque. A cuff that is either substantially completely transparent as taught by Geddes or substantially completely opaque as taught by Itonaga cannot (1) absorb the specific wavelengths of light emitted by the emitters to damp light piping but also allow for sufficient transmission of light through the cuff into and out of the appendage to properly illuminate the tissue and to properly detect the light back-scattered from the appendage; or (2) achieve attenuation such as to decrease the intensity of the piped light to below the governing SNR of the detectors.
10. Neither Geddes nor Itonaga teaches the bladder being made from a material tinted with pigments selected such that the bladder material will absorb the specific wavelengths of light emitted by the emitters to damp light piping but also allow for sufficient transmission of light through the cuff into and out of the appendage to properly illuminate the tissue and to properly detect the light back-scattered from the appendage; or the bladder being made from a material tinted with pigments selected such that the bladder material also will achieve attenuation such as to decrease the intensity of the piped light

to below the governing SNR of the detectors. It is therefore my opinion that even if Geddes's cuff 46 were made black as taught by Itonaga, the invention as disclosed and claimed in the present application would not result.

11. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (under 18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.
12. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Date: 7-17-06


David A. Bell